IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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Applicant	:	Shen-Ping Zhong et al.	
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Docket No.	:	1001.1728101	
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APPEAL BRIEF

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Assistant Commissioner for Patents
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By JoAnn Lindman

Pursuant to 37 C.F.R. § 41.37, Appellants hereby submit this Appeal Brief in furtherance of the Notice of Appeal filed on June 29, 2007 and of the Notice of Panel Decision from Pre-Appeal Review dated August 9, 2007 and Supplemental Notice of Panel Decision from Pre-Appeal Review dated October 26, 2007. Appellants authorize the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of $510.00 to be charged to Deposit Account No. 50-0413. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

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I. REAL PARTY IN INTEREST

The real party in interest in this appeal is SciMed Life Systems, Inc., a corporation organized and existing under the laws of the State of Minnesota, and having its principal offices at One Scimed Pace, Maple Grove, Minnesota 55311. An assignment from co-inventors Shen-Ping Zhong, Yem Chin, and Paul Scopton conveying all right, title and interest in the invention to SciMed Life Systems, Inc. has been recorded at Reel 015161, Frame 0489.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1-2, 4, 6, have been canceled without prejudice by prior Amendment, and claims 3, 5, and 7-52 remain pending in the application. Claims 3, 5, 7-17, 19-42 and 51-52 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Rau et al. (U.S. Patent No. 6,024,722) in view of Huntjens (U.S. Patent No. 3,388,095). Claims 45-50 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Rau et al. (U.S. Patent No. 6,024,722) in view of Huntjens (U.S. Patent No. 3,388,095) and further in view of Weissleder et al. (U.S. Patent No. 5,514,379). Claims 43-44 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Rau et al. (U.S. Patent No. 6,024,722) in view of Huntjens (U.S. Patent No. 3,388,095) and further in view of Lau et al. (U.S. Patent No. 6,517,570). The Appellant hereby appeals the final rejection of all pending claims 3, 5, and 7-52.

IV. STATUS OF AMENDMENTS

A Final Office Action was mailed December 29, 2006. An Amendment-After-Final was mailed on March 19, 2007, making amendments to the specification and claims 5, 22, 29, 51, and 52. An Advisory Action was mailed on April 2, 2007, which maintained the final rejection of claims 3, 5, and 7-52, but indicated that the Amendment-After-Final mailed on March 19, 2007 will be entered for purposes of Appeal.

A Notice of Appeal was filed on June 29, 2007, along with a Pre-Appeal Brief Request for Review. A Notice of Panel Decision was mailed August 9, 2007, maintaining the final rejection of claims 3, 5, and 7-52. All pending claims, namely claims 3, 5, and 7-52, are being appealed.

V. SUMMARY OF CLAIMED SUBJECT MATTER [1]

The present invention generally relates to elongate flexible elements of medical devices comprising a thermoplastic rigid rod polymer. Independent claim 3 recites a medical device comprising an elongate flexible element (see, for example, specification page 5, lines 15-22; page 6, lines 11-16; page 7, line 13-18; page 7, line 23-page 8, line 8; page lines 13-17; page 8, lines 20-21; page 11, line 14-page 12, line 4; reference numeral 4 of Figure 1; reference numeral 104 and 112 of Figures 2 and 3; reference numeral 304 of Figures 4 and 5; reference numeral 404 and 410 of Figure 6; reference numeral 510 of Figure 7; reference numeral 602 of Figure 8) made from a first polymer which is a substituted poly(1,4-phenylene) (see, for example, specification page 1, line 21-23; page 13, lines 17-18 and lines 20-21).

Independent claim 5 recites a medical device comprising an elongate flexible element (see, for example, specification page 5, lines 15-22; page 6, lines 11-16; page 7, line 13-18; page 7, line 23-page 8, line 8; page lines 13-17; page 8, lines 20-21; page 11, line 14-page 12, line 4; reference numeral 4 of Figure 1; reference numeral 104 and 112 of Figures 2 and 3; reference numeral 304 of Figures 4 and 5; reference numeral 404 and 410 of Figure 6; reference numeral 510 of Figure 7; reference numeral 602 of Figure 8) made from a first polymer which is a substituted poly(1,4-phenylene) (see, for example, specification page 1, line 21-23; page 13, lines 17-18 and lines 20-21) including a plurality of benzoyl substituted 1,4-phenylene units (see, for example, specification page 13, lines 20-21).

Independent claim 51 recites a medical device comprising a flexible elongate element (see, for example, specification page 5, lines 15-22; page 6, lines 11-16; page 7, line 13-18; page 7, line 23-page 8, line 8; page lines 13-17; page 8, lines 20-21; page 11, line 14-page 12, line 4; reference numeral 4 of Figure 1; reference numeral 104 and 112 of Figures 2 and 3; reference numeral 304 of Figures 4 and 5; reference numeral 404 and 410 of Figure 6; reference numeral

[1] The references to the specification and drawings provided herein are exemplary, and are not deemed to be limiting.

510 of Figure 7; reference numeral 602 of Figure 8), the flexible elongate element formed by the process comprising the steps of: providing a first polymer comprising a thermoplastic rigid rod polymer (see, for example, specification page 2, lines 3-4; page 5, lines 15-22; page 6, lines 11-16; page 7, line 13-18; page 7, line 23-page 8, line 8; page lines 13-17; page 8, lines 20-21; page 11, line 14-page 12, line 4); providing a second polymer compatible with the first polymer (see, for example, specification page 5, lines 20-22; page 6, lines 4-9; page 7, lines 15-18 and 20-21; page 8, lines 13-14); co-extruding the first polymer with the second polymer (see, for example, specification page 2, lines 22-23; page 3, line 7-8; page 6, lines 4-9); and not cross-linking the first polymer while cross-linking the second polymer (see, for example, specification page 6, lines 6-7; page 8, lines 17-19; page 10, lines 3-9; page 11, line 19-page 12, line 4).

Independent claim 52 recites a medical device comprising a flexible elongate element (see, for example, specification page 5, lines 15-22; page 6, lines 11-16; page 7, line 13-18; page 7, line 23-page 8, line 8; page lines 13-17; page 8, lines 20-21; page 11, line 14-page 12, line 4; reference numeral 4 of Figure 1; reference numeral 104 and 112 of Figures 2 and 3; reference numeral 304 of Figures 4 and 5; reference numeral 404 and 410 of Figure 6; reference numeral 510 of Figure 7; reference numeral 602 of Figure 8), the flexible elongate element formed by the process comprising the steps of: providing a first polymer comprising a thermoplastic rigid rod polymer (see, for example, specification page 2, lines 3-4; page 5, lines 15-22; page 6, lines 11-16; page 7, line 13-18; page 7, line 23-page 8, line 8; page lines 13-17; page 8, lines 20-21; page 11, line 14-page 12, line 4); providing a second polymer compatible with the first polymer (see, for example, specification page 5, lines 20-22; page 6, lines 4-9; page 7, lines 15-18 and 20-21; page 8, lines 13-14); co-extruding the first polymer with the second polymer (see, for example, specification page 2, lines 22-23; page 3, line 7-8; page 6, lines 4-9); and cross-linking both the first polymer and the second polymer (see, for example, specification page 6, lines 6-7; page 8, lines 17-19; page 10, lines 3-9; page 11, line 19-page 12, line 4).

VI. GROUNDS OF REJECTIONS TO BE REVIEWED ON APPEAL

1. Whether claims 3, 5, 7-17, 19-42, and 51-52 are unpatentable under 35 U.S.C. § 103(a) over Rau et al. (U.S. Patent No. 6,024,722) in view of Huntjens (U.S. Patent No. 3,388,095).

2. Whether claims 45-50 are unpatentable under 35 U.S.C. § 103(a) over Rau et al. (U.S. Patent No. 6,024,722) in view of Huntjens (U.S. Patent No. 3,388,095) and further in view of Weissleder et al. (U.S. Patent No. 5,514,379).

3. Whether claims 43-44 are unpatentable under 35 U.S.C. § 103(a) over Rau et al. (U.S. Patent No. 6,024,722) in view of Huntjens (U.S. Patent No. 3,388,095) and further in view of Lau et al. (U.S. Patent No. 6,517,570).

VII. ARGUMENT

A. Claims 3, 5, 7-17, 19-42, and 51-52 are patentable over Rau et al. (U.S. Patent No. 6,024,722) in view of Huntjens (U.S. Patent No. 3,388,095) under 35 U.S.C. § 103(a).

In paragraph 5 of the Final Office Action, the Examiner rejected claims 3, 5-17, 19-42, and 51-52 under 35 U.S.C. 103(a) as being unpatentable over Rau et al. in view of Huntjens. In rejecting claims under 35 U.S.C. § 103, the Examiner bears the burden of establishing a prima facie case of obviousness. *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984). "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007) (*citing In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)). Furthermore, where the Examiner relies on a combination of disclosures, the Examiner must provide sufficient evidence to show that one having ordinary skill in the art would have done what Appellant did. *United States v. Adams*, 383 U.S. 39 (1966); *In re Kahn*, 441 F.3d 977, 987-988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006); *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick, Co.*, 464 F.3d 1356, 1360-1361, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006). The mere fact that all the claimed elements or steps appear in the prior art is not per se sufficient to establish that it would have been obvious to combine those elements. *United States v. Adams*, *Id.*; *Smith Industries Medical Systems, Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1356, 51 USPQ2d 1415, 1420 (Fed. Cir. 1999).

1. Claim 3 is patentable over Rau et al. in view of Huntjens.

Referring to claim 3, which recites:

3. A medical device comprising an elongate flexible element made from a first polymer which is a substituted poly(1,4-phenylene).

In formulating the rejection of claim 3, the Examiner asserted that Rau discloses a polymer that can "contain a substantial number of polyvalent aromatic groups such as polyphenylene." See Rau, at column 9, lines 64-66. The Examiner then suggests "Huntjens disclose a polymer with phenylene units comprising 1,4 polyphenylene." See Office Action, December 29, 2006, page 3. The Office Action goes on to state that it "would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a polymer comprising substituted 1,4 polyphenylene in Rau et al in order to obtain articles having unique physical properties over a broad temperature range as taught in Huntjens." See Office Action, December 29, 2006, page 3. Appellants respectfully disagree with this assessment, asserting there is no motivation to make the proposed modification as suggested in the rejection. The Examiner has failed to provide articulated reasoning with some rational underpinning to support the legal conclusion of obviousness, as is required.

Rau seems to teach a shaft which may include a layer formed of a polyimide/liquid crystal polymer blend. See Rau, at column 9, lines 55-62. Rau goes on to state liquid crystal polymers "are rigid, rod-like macromolecules which typically contain a substantial number of polyvalent aromatic groups such as phenylene." Rau, column 9, lines 63-66. Thus, it is a class of liquid crystal polymers which is disclosed regarding the identified portion of Rau.

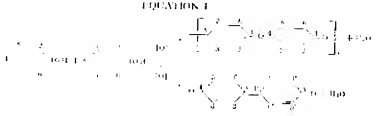
Huntjens seems to teach a stabilized poly(2,6-dimethyl-1,4-phenylene)ether composition. See Huntjens, at column 1, lines 19-20. Huntjens seems to be concerned with the instability of poly(2,6-dimethyl-1,4-phenylene)ether compositions, stating "the polymer has been subject to embrittlement and discoloration when exposed to elevated temperatures in the presence of oxygen." Huntjens, at column 1, lines 27-31. Huntjens discloses adding a minor portion of a 2-mercaptobenzimidazole to a composition containing poly(2,6-dimehtyl-1,4-phenylene) to provide stability of the composition. See Huntjens, at column 1, lines 62-67. Huntjens states that poly(2,6-dimethyl-1,4-phenylene)ether is "one of a number of polyphenylene ethers disclosed and claimed in co-pending U.S. Patents Nos. 3,306,874 and 3,306,875." See Huntjens, at column 1, lines 21-24. Upon examination of the contents of these documents, Appellants

respectfully note that these patents are directed to the oxidation of phenols, as evidenced in their respective titles. More precisely, Patent No. 3,306,874 states that:

> The overall oxidation reaction to which my invention is directed is a reaction involving the hydrogen atom of the phenolic group of the phenol molecule, a hydrogen, chlorine, bromine, or iodine substituent in the para (4-) position of the phenol molecule and oxygen with the formation of water and polyarylene ethers (more specifically polyphenylene ethers) and/or diphenoquinones according to the following schematic diagram:

Similarly, Patent No. 3,306,875 states:

> The overall oxidation reaction to which my invention is directed is a reaction involving the hydrogen atom of the phenolic group of the phenol molecule, a hydrogen, chlorine, bromine, or iodine substituent in the ortho (2-) or para (4-) position of the phenol molecule and oxygen with the formation of water according to the following schematic diagram using the para position for purposes of illustration:



From the teachings of U.S. Patent Nos. 3,306,874 and 3,306,875, it seems apparent that the composition disclosed in Huntjen, namely that of stabilized poly(2,6-dimethyl-1,4-phenylene)ether, is an ether having a carbon-oxygen-carbon bond, and does not possess the molecular structure of a liquid crystal polymer of the type disclosed in Rau. It follows that one of ordinary skill in the art would not be inclined to substitute the stabilized polymeric composition disclosed in Huntjen (an ether), which does not possess the molecular structure of a liquid crystal polymer and thus is not considered a liquid crystal polymer, for a liquid crystal

polymer disclosed in Rau. One of skill in the art would understand that the ether compound taught in Huntjen does not have similar physical characteristics sought by the inclusion of a liquid crystal polymer. Therefore, there simply is no motivation to make such a modification. One of ordinary skill in the art would not be inclined to look to teachings regarding the stabilization of a poly(2,6-dimethyl-1,4-phenylene)ether composition in an attempt to find a substitution for a liquid crystal polymer component of a device.

It follows that in reviewing the teachings of Huntjens, it is apparent that Huntjens is not in the field of the Appellants' endeavor, nor is its teachings reasonably pertinent to the particular problem with which the present invention is concerned. Namely, Huntjens is specifically concerned with the stabilization of a poly(2,6-dimethyl-1,4-phenylene)ether composition. Dissimilarly, the present application is primarily concerned with achieving the requirements of high levels of pushability, torqueability, and/or flexibility of medical devices. See Specification, page 1, lines 9-17. This is specifically reflected by claim 3, which is directed to a "medical device."

Appellants assert the Examiner has impermissibly collected various prior art documents in formulating the rejection without considering the inventive contributions attributed to the present application. In assessing the contributions of Huntjens, it appears as though the Examiner has simply found a reference which discloses a composition including 1,4 phenylene monomers, while disregarding the specific application or taking into account the absence of motivation to make the proposed modification.

An essential inquiry in attempting to establish a *prima facie* case of obviousness is "to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." M.P.E.P. §2143.01, quoting *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972). The mere fact that all the claimed elements or steps appear in the prior art is not per se sufficient to establish that it would have been obvious to combine those elements. *United States v. Adams*, *Id.*; *Smith Industries Medical Systems, Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1356, 51 USPQ2d 1415, 1420 (Fed. Cir. 1999). Appellants assert that the prior art provides no motivation to make the proposed modification. One of skill in the art, informed of the teachings of Rau and Huntjens, would not be inclined to arrive at that

which is currently claimed, namely a medical device comprising an elongate flexible element made from a first polymer which is a substituted poly(1,4-phenylene).

Furthermore, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007) (*citing In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)). Furthermore, where the Examiner relies on a combination of disclosures, the Examiner must provide sufficient evidence to show that one having ordinary skill in the art would have done what Appellant did. *United States v. Adams*, 383 U.S. 39 (1966); *In re Kahn*, 441 F.3d 977, 987-988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006); *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick, Co.*, 464 F.3d 1356, 1360-1361, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006). In the Advisory Action, the Examiner stated, "it would have been obvious for one of ordinary skill in the art to provide for 1,4 polyphenylene units as the phenylene units in Rau et al to provide for desired properties over a wide temperature range as taught by Huntjens" and "it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice". However, none of these provide sufficient evidence to show that one or ordinary skill in the art would have done what the Appellant did nor do they provide articulate reasoning with some rational underpinning. Appellants assert that the prior art provides no motivation to make the proposed modification. One of skill in the art, informed of the teachings of Rau and Huntjens, would not be inclined to arrive at that which is currently claimed, namely a medical device comprising an elongate flexible element made from a first polymer which is a substituted poly(1,4-phenylene).

In the Final Office Action of December 29, 2006, on page 3, the Examiner asserts that it would have been obvious to use the poly(2,6-dymethyl-1,4-phenylene) ether of Huntjens in the catheter of Rau et al. because Huntjens teaches "articles having unique physical properties over a broad temperature range (column 1, line 25" and therefore, "one of ordinary skill in the art would therefore have recognized the advantage of providing for the substituted 1,4 polyphenylene of Huntjens in Rau et al.."

However, one of ordinary skill would have recognized no advantages of using the polyphenylene ether of Huntjens in the catheter of Rau et al. A teaching that the polyphenylene ether has "a unique combination of...properties" (Huntjens at column 1, lines 24-26) is little more than puffery and would not have motivated one of skill in the art to make the suggested substitution. Moreover, if the polyphenylene ether of Huntjens has a unique combination of properties, it cannot have the same properties as those polymers already disclosed by Rau et al. as suitable for use with their catheter. Appellants can find no teaching in Huntjens which would suggest that the polyphenylene ether is more suitable than those polymers already disclosed by Rau et al. The teaching that polyphenylene ether can be used over a broad range of temperatures is of little interest to one making the catheter of Rau et al. This catheter is a balloon catheter used in body vessel lumens and, as such, Appellants understand it to be exposed only to a relatively narrow range of temperatures centering about normal body temperature and this only for a limited period of time. There is thus nothing that Appellants can find in the teachings of Huntjens that would motivate one to substitute its polymer for that of Rau et al.

For at least these reasons, claim 3 is believed to be patentable over Rau et al. in view of Huntjens. For similar reasons, as well as others, claims 7-42 which depend from claim 3 and include significant additional limitations, are believed presently in condition for allowance. Accordingly, Appellants respectfully request reversal of the rejection.

2. Claim 5 is patentable over Rau et al. in view of Huntjens.

Referring to claim 5, which recites:

> 5. A medical device comprising an elongate flexible element made from a first polymer which is a substituted poly(1,4-phenylene) including a plurality of benzoyl substituted 1,4-phenylene units.

In the Final Office Action, the Examiner acknowledges that Rau fails to disclose a polymer comprising benzoyl substituted 1,4 phenylene units. See Office Action, December 29, 2006, page 3. However, the Examiner states that "[i]t would have been obvious...to have selected benzoyl substituted 1,4 phenylene units, as benzoyl substituted 1,4 phenylene units are

among the known phenylene units." Office Action, December 29, 2006, pages 3-4. Appellants must respectfully disagree. Appellants respectfully assert that this statement is purely conclusary, and the Examiner has provided no documentary evidence in support of this assertion in accordance with M.P.E.P. §2144.03. Appellants note that the substituted portion of the poly(1,4-phenylene) can provide different properties, depending on what the poly(1,4-phenylene) is substituted with. Thus, it would not have been obvious to have selected a substituted poly(1,4-phenylene) polymer including a plurality of benzoyl substituted 1,4 phenylene units.

Additionally, where the prior art discloses only a genus such as polymers containing a substantial number of polyvalent aromatic groups such as phenylene, the MPEP provides guidelines for determining the obviousness of a species (here benzoyl substituted 1,4 phenylene units) when the prior art teaches only the genus. MPEP 2144.08 states that "office personnel should [first] attempt to find additional prior art to show that the differences between the prior art primary reference and the claimed invention as a whole would have been obvious. Where such additional prior art is not found, Office personnel should follow these guidelines to determine whether a single reference 35 U.S.C. 103 rejection would be appropriate." The steps the Examiner is instructed to take by the MPEP in such a case include determining whether one of skill in the art would have been motivated to select the claimed species or subgenus by considering, among other factors, the size of the genus and the express teachings. Appellants understand phenylene to be a rather basic group which can be a constituent of many polymers, of which poly (1,4 phenylene) is only one. Similarly, benzoyl is but one functional group among many dozens of functional groups. There are consequently hundreds of subgenuses and species in the genus disclosed by Rau et al. Therefore, where there is no express teaching to use poly (1,4 phenylene) or to use benzoyl substituted poly (1,4 phenylene) in the cited reference or other teaching cited by the Examiner to use the claimed material over the many alternative polyphenlyne polymers, there is no showing of obviousness.

Therefore, for at least these reasons, claim 5 is believed to be patentable over Rau et al. in view of Huntjens. Accordingly, Appellant respectfully requests that the rejection of claim 5 be reversed.

3. Claim 51 is patentable over Rau et al. in view of Huntjens.

Referring to claim 51, which recites:

> 51. A medical device comprising a flexible elongate element, the flexible elongate element formed by the process comprising the steps of:
> providing a first polymer comprising a thermoplastic rigid rod polymer;
> providing a second polymer compatible with the first polymer;
> co-extruding the first polymer with the second polymer; and
> not cross-linking the first polymer while cross-linking the second polymer.

In formulating the rejection, the Office Action states that "Rau et al disclose that the medical device, comprising a crosslinkable polymer, is known in the art (thermoset polyimide; column 1, line 43); Rau et al therefore disclose a second polymer which is crosslinked or is not crosslinked." Appellants respectfully disagree with this assessment of the teachings of Rau.

Appellants agree that Rau discloses the use of thermoset polyimide. However, Rau's inventive contributions are directed to thermoplastic polyimide ("It is the primary purpose of this invention to apply thermoplastic polyimide to the art of balloon catheter construction." See Rau, at column 2, lines 30-32.). Rau merely identifies thermoset polyimide in order to distinguish thermoplastic polyimide from thermoset polyimide as discussed briefly in the background section of the disclosure. In fact, regarding thermoset polyimide, Rau states:

> One material of choice for such catheters has been thermoset polyimide, primarily because of its high strength and flexibility in small diameter with very thin walls. Being thermoset, the polyimide used heretofore has involved complicated manufacturing procedures due to the fact that it is insoluble and "intractable" i.e., not meltable.

Rau, at column 1, lines 33-38. Thus, Rau expressly states that thermoset polyimide is not meltable. Futhermore, regarding advantages of thermoplastic materials over thermoset polyimide Rau states:

> [t]hermoplastic materials lend themselves to simpler manufacturing techniques, such as extrusion in forming shafts and blow molding in forming the balloons than do the aforementioned thermoset polyimide materials due to the fact that they are soluble and meltable.

Rau, at column 1, lines 61-65. Thus, in view of that disclosed in Rau, one skilled in the art would conclude that thermoset polyimide is not extrudable, thus could not meet the emphasized limitations of claim 51. Namely, the identified passage of Rau is insufficient for disclosing the

limitations of claim 51 of "co-extruding the first polymer with the second polymer" and "not cross-linking the first polymer while cross-linking the second polymer." At no point throughout the document does Rau suggest the inclusion of a thermoset polyimide in a disclosed embodiment.

Additionally, the alleged disclosure in Rau et al. of a polymer that may or may not be cross-linked does not show the claim element of not cross-linking a first polymer while cross-linking a second polymer as recited in claim 51. In fact, on page 6 of the Final Office Action, the Examiner makes a contradictory (but nevertheless incorrect) assertion with regard to claim 51, saying that "the first polymer disclosed by Rau et al. is a rigid rod polymer as discussed above, and is extruded as discussed above, and is therefore cooled from an extrusion process; Rau et al. therefore disclose a first polymer that is crosslinked." With regards to claims 51 and 52, therefore, the Examiner is making two mutually contradictory statements: that Rau et al. teaches that the first polymer is crosslinked and that Rau et al. teaches that the first polymer is not crosslinked. In fact, what Rau et al. teach as to the first polymer is irrelevant in this rejection, because the Examiner has indicated on page 3 that the first polymer is considered to be the polyphenylene ether of Huntjens, which Rau et al. teaches nothing about. The Examiner has failed, therefore to demonstrate that the combination of Rau et al. and Huntjens teach or suggest each and every element of these claims and consequently the Examiner has not made a prima facie case of obviousness.

Therefore, for at least these reasons, claim 51 is believed patentable over the cited art. Accordingly, Appellant respectfully requests that the rejection is overruled.

4. Claim 52 is patentable over Rau et al. in view of Huntjens.

In formulating the rejection of claim 52, it was stated in the Office Action that noted limitations of claim 52 "is given little patentable weight as it is directed to process limitation rather than a structural limitation." Office Action, December 29, 2006, at page 6. Although Appellants agree with the Examiner that apparatus claims must be structurally distinguishable from the prior art, Appellants respectfully note that the statement provided in the Office Action is in conflict with the guidelines provided in the Manual of Patent Examination Procedure. Section 2114 of the M.P.E.P. states, "[w]hile features of an apparatus may be recited either structurally

or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." M.P.E.P. §2114, citing *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Despite the guidelines of the M.P.E.P., the Examiner appears to give no patentable weight to the limitations recited in claim 52.

Claim 52 recites:

> A medical device comprising a flexible elongate element, the flexible elongate element formed by the process comprising the steps of:
> providing a first polymer comprising a thermoplastic rigid rod polymer;
> providing a second polymer compatible with the first polymer;
> *co-extruding the first polymer with the second polymer; and*
> *cross-linking both the first polymer and the second polymer.*

(Emphasis added). Thus, the flexible elongate element of the medical device is formed of a cross-linked first polymer and a cross-linked second polymer, clearly structural limitations of the medical device. The morphology of a polymer which has been cross-linked is clearly dissimilar from that of a polymer which has not undergone cross-linking. The molecular structure of a polymer is clearly a structural attribute of the polymer. Thus, as evidenced in the Office Action, structural limitations of claim 52 have not been adequately addressed in formulating the rejection.

Appellants note the remarks presented above regarding the allowability of claim 51 are equally applicable to claim 52, and thus reference to the above remarks is duly made. For at least these reasons claim 52 is believed patentable over the cited art. Accordingly, Appellants respectfully request that the rejection is reversed.

B. *Claims 45-50 are patentable over Rau et al. (U.S. Patent No. 6,024,722) in view of Huntjens (U.S. Patent No. 3,388,095) and further in view of Weissleder et al. (U.S. Patent No. 5,514,379) under 35 U.S.C. § 103(a).*

Claims 45-50 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Rau et al., U.S. Patent No. 6,024,722, in view of Huntjens, U.S. Patent No. 3,388,095, and further in view of Weissleder et al., U.S. Patent No. 5,514,379. Appellants respectfully traverse this rejection.

As asserted above, there is no motivation to combine the teachings of Huntjens with those of Rau. Furthermore, Weissleder fails to provide the requisite motivation to establish a *prima facie* case of obviousness. For at least this reason, claims 45-50 are believed to be in condition for allowance. Withdrawal of the rejection is respectfully requested.

C. Claims 43 and 44 are patentable over Rau et al. (U.S. Patent No. 6,024,722) in view of Huntjens (U.S. Patent No. 3,388,095) and further in view of Lau et al. (U.S. Patent No. 6,517,570) under 35 U.S.C. § 103(a).

Claims 43-44 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Rau et al., U.S. Patent No. 6,024,722, in view of Huntjens, U.S. Patent No. 3,388,095, and further in view of Lau et al., U.S. Patent No. 6,517,570. Appellants respectfully traverse this rejection.

As asserted above, there is no motivation to combine the teachings of Huntjens with those of Rau. Furthermore, Lau fails to provide the requisite motivation to establish a *prima facie* case of obviousness. For at least this reason, claims 43-44 are believed to be in condition for allowance. Withdrawal of the rejection is respectfully requested.

VIII. CONCLUSION

For the reasons stated above, the Examiner's rejections of claims 3, 5, and 7-52 under 35 U.S.C. § 103(a) should be overruled.

Respectfully submitted,

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By their Attorney,

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IX. CLAIMS APPENDIX

3. A medical device comprising an elongate flexible element made from a first polymer which is a substituted poly(1,4-phenylene).

5. A medical device comprising an elongate flexible element made from a first polymer which is a substituted poly(1,4-phenylene) including a plurality of benzoyl substituted 1,4-phenylene units.

7. The medical device of claim 3, wherein the medical device is an intravascular guidewire.

8. The medical device of claim 7, wherein the elongate flexible element is a core wire.

9. The medical device of claim 8, wherein the core wire extends from a position proximate the proximal end of the guidewire to a position proximate the distal end of the guidewire.

10. The medical device of claim 8, wherein the core wire comprises a plurality of elongate longitudinally extending threads made from the polymer.

11. The medical device of claim 8, wherein a substantial length of the core wire has a circular cross sectional shape.

12. The medical device of claim 8, wherein a substantial length of the core wire has a rectangular cross sectional shape.

13. The medical device of claim 8, wherein a substantial length of the core wire has a cruciate cross sectional shape.

14. The medical device of claim 8, wherein the elongate flexible element is a sleeve extending over the core wire.

15. The medical device of claim 14, further comprising a second sleeve disposed on the first, the second sleeve made from the polymer.

16. The medical device of claim 14, wherein the sleeve is an extruded tube.

17. The medical device of claim 14, wherein the sleeve is a coil.

18. The medical device of claim 17, wherein the sleeve is formed from a wound flat tape.

19. The medical device of claim 14, wherein the sleeve is a mesh.

20. The medical device of claim 14, wherein the sleeve is a weave.

21. The medical device of claim 3, wherein the medical device is a catheter.

22. The medical device of claim 21, wherein the flexible elongate element is a sleeve.

23. The medical device of claim 22, further comprising a second sleeve disposed on the first, the second sleeve made from the polymer.

24. The medical device of claim 22, wherein the sleeve is an extruded tube.

25. The medical device of claim 22, wherein the sleeve is a coil.

26. The medical device of claim 25, wherein the sleeve is formed from a wound flat tape.

27. The medical device of claim 22, wherein the sleeve is a mesh.

28. The medical device of claim 22, wherein the sleeve is a weave.

29. The medical device of claim 22, further comprising an inner sleeve and an outer sleeve, the flexible elongate element comprising a plurality of elongate threads disposed between the inner sleeve and the outer sleeve.

30. The medical device of claim 3, wherein the elongate flexible element comprises a blend of the first polymer and a second polymer.

31. The medical device of claim 3, wherein the medical device comprises a second polymer, wherein the first polymer is not cross-linked and the second polymer is cross-linked.

32. The medical device of claim 3, wherein the medical device comprises a balloon.

33. The medical device of claim 32, wherein the elongate flexible element is a balloon sleeve.

34. The medical device of claim 33, wherein the balloon sleeve comprises a second polymer.

35. The medical device of claim 34, wherein the first polymer and the second polymer are blended.

36. The medical device of claim 34, wherein the first polymer and the second polymer are coextruded.

37. The medical device of claim 34, wherein the first polymer is in a first layer and the second polymer is in a second layer.

38. The medical device of claim 37, wherein the first layer has a distal varying thickness to create a first region having a first compliance and a second region having a second compliance less than the first compliance.

39. The medical device of claim 34, wherein the first polymer comprises a mesh or weave disposed in a layer comprising the second polymer.

40. The medical device of claim 34, wherein the first polymer is not cross-linked and the second polymer is cross-linked.

41. The medical device of claim 33, wherein the medical device is an intravascular balloon catheter and the balloon sleeve has a thickness of 0.25 to 5.0 mil.

42. The medical device of claim 41, wherein the balloon sleeve has a thickness of 0.3 to 1.0 mil.

43. The medical device of claim 3, wherein the elongate member comprises a plurality of struts forming a stent.

44. The medical device of claim 43, wherein the stent is a self-expanding stent.

45. The medical device of claim 43, wherein the stent further comprises a hydrogel coating.

46. The medical device of claim 45, wherein the hydrogel coating includes a therapeutic agent.

47. The medical device of claim 3, wherein the elongate member comprises a paramagnetic materials.

48. The medical device of claim 47, wherein the paramagnetic material is gadolinium (III).

49. The medical device of claim 3, further comprising a lubricous sheath disposed around the elongate member.

50. The medical device of claim 48, wherein the lubricious sheath comprises a hydrogel polymer.

51. A medical device comprising a flexible elongate element, the flexible elongate element formed by the process comprising the steps of:

providing a first polymer comprising a thermoplastic rigid rod polymer;

providing a second polymer compatible with the first polymer;

co-extruding the first polymer with the second polymer; and

not cross-linking the first polymer while cross-linking the second polymer.

52. A medical device comprising a flexible elongate element, the flexible elongate element formed by the process comprising the steps of:

providing a first polymer comprising a thermoplastic rigid rod polymer;

providing a second polymer compatible with the first polymer;

co-extruding the first polymer with the second polymer; and

cross-linking both the first polymer and the second polymer.

X. EVIDENCE APPENDIX

None

XI. RELATED PROCEEDINGS APPENDIX

None